



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER**

**PROTOCOL No.:**

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**1.0 PROTOCOL APPROVAL:**

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following signatories.

This Installation Qualification protocol of Bin blender has been reviewed and approved by the following signatories:

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



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**2.0 OVERVIEW:**

**2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Bin blender and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the Bin blender was installed as required in area Blender 1200 ltr.

**2.2 PURPOSE:**

The purpose of this protocol is to establish documentary evidence to ensure that the Bin blender received matches the Design specification and also to ensure that it is properly and safely installed.

**2.3 SCOPE:**

This Protocol is applicable to installation of Bin blender in blender 1200 ltr. area of the manufacturing facility.

**2.4 RESPONSIBILITY:**

In accordance with protocol, following functions shall be responsible for the qualification of system.

**Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:**

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- The production operator / supervisor shall carry out the cleaning and operation of machine.

**Head – Production/ Engineering:**

- Review of protocol, the completed qualification data package, and the final report.



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- Assist in the resolution of validation deficiencies.

**Head – Operation and Quality Assurance:**

- Review and approval of protocol, the completed qualification data package, and the final report.





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**3.0 ACCEPTANCE CRITERIA:**

- 3.1 The Bin blender shall meet the system description given in design specification.
- 3.2 The Bin blender shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.

**4.0 REVALIDATION CRITERIA:**

The machine has to be revalidated if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown, maintenance is carried out.
- As per revalidation date and schedule.

**5.0 INSTALLATION QUALIFICATION PROCEDURE**

**5.1 EQUIPMENT DESCRIPTION:**

Equipment Name	:	Bin blender
Supplier / Manufacturer	:	
Capacity	:	1200 L / 600 L
Serial No.	:	
Location	:	Blender-1200 Ltr.

**Brief Description:**

GMP model Bin blender is unique, versatile equipment used for lubricating/ blending the granules/ powder.

The equipment comprises main SS clad column, drive assembly, bearing housing, arm assembly, hydraulic cylinder & bin.

The main column is sandwiched between floors & slab. The double acting hydraulic cylinder is located centrally inside the column & bearing housing is mounted on hydraulic cylinder. Adapting this double acting hydraulic cylinder the bin can lift to & lower down to discharge the product after blending operation.



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The main shaft i.e. drive shaft is located in the bearing housing, at rear end of drive shaft the direct mounting inline helical gear box of/ Siemens make is fixed & the motor is directly fastened on the gear box. Because of this drive assembly the chain sprocket & V belt pulley design is discarded & it saves the unwanted lubrication & frictional loss. At the other end i.e. front side of drive shaft the arm assembly is located where blender bin can easily be engaged & dis-engaged.

The prime mover will be coupled directly with in line helical gear box. The output shaft of gear box will be connected to blender drive shaft. By this coupling the blender output RPM will be achieved 5-10 RPM.

The drive assembly is located inside the column & front opening of column is covered with nylon belt by which cGMP factor is maintained.

The arm assembly is provided with gate & locking bolt & wheel type nut. By maintaining the required height & proper level of the arm both bins can be slide easily & hold inside the arm with the help of the gate locking arrangement.

The main panel is located at service floor & all the related cables are routed through slab & column from main panel to operator panel. The operator panel is provided on machine column for easy approachability of operation.

The safety guards are provided around the blender with safety limit switch. The acting hydraulic cylinder is unique feature of this equipment & pilot operated anti-burst, non-return valve provided on cylinder port is a safety factor of this equipment. The power pack enclosure having hydraulic components & motor will be located inside the mast.



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**5.2 INSTRUCTION FOR FILLING THE CHECKLIST:**

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.





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**5.3 INSTALLATION CHECKLIST:**

Installation checklist is as follows:

S.No.	Statement	Method of verification	Actual observation	Checked By Sign/Date
1.	Verify the purchase order.	Physically		
2.	Verify that the "As Built" drawing is complete and represents the design concept.	Physically		
3.	Verify that major components are securely anchored and shock proof.	Physically		
4.	Verify that there is no observable physical damage.	Physically		
5.	Verify that there is sufficient room provided for servicing.	Physically		
6.	Verify that all piping and electrical connections are done according to the drawings.	Physically		
7.	All access ports are examined and cleared of any debris.	Physically		
8.	Safe electrical connections.	Physically		
9.	Wiring diagram affixed to inside section of control panel.	Physically		
10.	Equipment identification nameplate visible.	Physically		
11.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.4 IDENTIFICATION OF MAJOR COMPONENTS:**

Describe each critical component and check them and fill the inspection checklist.

<b>System Components</b>	<b>Design Specification</b>		<b>Method of Verification</b>	<b>Observation</b>	<b>Verified By Sign/Date</b>
<b>Equipment Description</b>	Name	Bin blender-1200/600 ltrs.	Verified with name plate		
	Make	SAAN Engineers Pvt. Ltd.	Verified with name plate		
	Model	BB-1200/600 Ltrs.	Verified with name plate		
	Sr. No.	012/14-2015	Verified with name plate		
	Dimension (Supporting main column)	600 x 900 x 3300 mm Ht.	Physically by measurement/ Technical Certificate		
	Location	Blender 1200 Ltr.	Visually /physically		
<b>Gear Box</b>	Make	Siemens	Visually /physically		
	Spec.	Model- K-108 Ratio- 138.87:1	Visually /physically		
<b>Motor For Blending</b>	Make	Hindustan	Visually /physically		
	Spec.	7.5 HP/ 5.5 KW, 1450 RPM, Non-FLP	Visually /physically		
	Sr. No.	1114M489018	Visually /physically		
<b>Motor For Lifting</b>	Make	HMM	Visually /physically		
	Spec.	2 HP, 1420 RPM, 3 Ph, TEFC	Visually /physically		
	Sr. No.	1014M483624	Visually /physically		
<b>Proximity Sensor</b>	Make	Electroquip	Visually /physically		
	Spec.	PNP- 24 VDC/18	Visually /physically		
<b>Hydraulic</b>	Make	Rexroth	Visually /physically		



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<b>Pump</b>	Spec.	Model- 6cc/Rev	Visually /physically		
<b>Hydraulic Solenoid Valve</b>	Make	Rexroth	Visually /physically		
	Spec.	Model- 4WE6E62EG24N9K 4	Visually /physically		
<b>Flow Control Valve</b>	Make	Shakti	Visually /physically		
	Spec.	SVR-12	Visually /physically		
<b>Check Valve</b>	Make	Integrated	Physically/ Test Certificate		
	Spec.	4ck-30	Physically/ Test Certificate		
<b>Pressure Gauge</b>	Make	Shreeji	Visually /physically		
	Spec.	Model- 0- 280 Kg/ Cm <sup>2</sup>	Visually /physically		
<b>Pressure Relief Valve</b>	Make	Prism	Visually /physically		
	Spec.	Model- 06- 200 BAR	Physically/ Test Certificate		
<b>Power Panel</b>	Description	Floor- mounted type located on service floor	Visually /physically		
	Parts	Mains ON/ OFF Switch, MCB, Indication Lamp (R, Y, B), SMPS, AC Drive (VFD)	Visually /physically		
<b>SMPS</b>	Spec.	24 Volts DC	Visually /physically		
<b>VFD</b>	Make	Mitsubishi	Visually /physically		
	Spec.	FRD-740-120EC	Visually /physically		
<b>Operating Panel</b>	Parts	ON/ OFF Selector Switch, Enable/disable Selector switch, UP/DOWN Switch, Emergency Switch,	Visually /physically		



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		RUN/STOP Switch, Speed regulating rotary Switch, VFD fault Hooter			
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**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:** should be verified by test certificates of respective material apart from that SS material should be verified by molybdenum kit in absence of test certificate.

<b>Name of Components</b>	<b>Material of Construction</b>	<b>Method of Verification</b>	<b>Observation</b>	<b>Checked By Sign/Date</b>
Side covers Guards & paneling.	SS 304	Molybdenum kit/ Test Certificate		
Bin	SS 316	Molybdenum kit/ Test Certificate		
Man way Cover	SS 316	Molybdenum kit/ Test Certificate		
Discharge Valve	SS 316	Molybdenum kit/ Test Certificate		
Charging Nozzle and Dummy	SS 316	Molybdenum kit/ Test Certificate		
Air Vent Nozzle and Dummy	SS 316	Molybdenum kit/ Test Certificate		
Main Column	MS with SS 304 cladded.	Molybdenum kit/ Test Certificate		
Arm Assembly	SS 304.	Molybdenum kit/ Test Certificate		
Main Shaft	En – 8 Precision	Physically/ Test Certificate		
Support Pendent	MS Painted	Physically		
Guide Roller	MS Painted	Physically		
Carriage Assembly	MS Painted	Physically		
Carriage Rollers	MS Plated	Physically		



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Gear Box Mounting Plate	MS painted	Physically		
Safety Railing	SS 304	Molybdenum kit/ Test Certificate		
Power Panel ( Main Panel)	MS Powder coated	Physically		
Control Panel ( Operation)	SS 304	Molybdenum kit/ Test Certificate		
Power pack Sump	MS Powder coated	Physically		
Power pack Enclosure	MS Powder coated	Physically		
Gasket	Food grade silicone rubber	Test Certificate		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.6 IDENTIFICATION OF SUPPORTING UTILITIES:**

Utility	Method of verification	Observation	Checked by Sign/ Date
<b>Electricity:</b> 3 phase, 415 $\pm$ 5% V AC, 50 Hz $\pm$ 5% supply with neutral and proper earthing	Physically		
<b>Compressed Air:</b> 5-6 Kg/Cm <sup>2</sup>	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.7 IDENTIFICATION OF SAFETY FEATURES:** Identify and record the safety features (if any) and their function in following tables:

Safety Features Description	Function	Method of Verification	Observation	Checked By Sign/ Date
Machine emergency stop	To stop machine immediately in case of emergency	Physically		
Safety guard (Manual) for moving blender & acting as a jumper for earth continuity	For equipment & operation safety	Physically		
Up proximity switch	To stop the machine at high reach	Physically		



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Down proximity switch	To limit the minimum lift & to perform blending. Machine does not start if it is in down position.	Physically		
Position proxy	To stop the blender bin at its home position after blending operation gets over	Physically		
Anti burst POC non returnable valve	To avoid sudden fall due to hydraulic failure	Physically		
Variable frequency drive	1) To protect the blender motor against over load 2) To select/ change the blending RPM 3) For soft start/ stop	Physically		
Limit switches	For access safety guard to shut- off the system	Physically		
Motor overload relay (for lifting motor)	For motor safety/ protection	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**





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**5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED:**

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):**

The following Standard Operating Procedures were identified as important for effective performance of Bin blender.

S.No.	SOP TITLE	IDENTIFIED BY	DATE

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.10 VERIFICATION OF DRAWING AND DOCUMENTS:**

Following documents are reviewed and attached as listed below:

S.No.	DRAWING AND DOCUMENT DETAIL	CHECKED BY (SIGN)	DATE

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.11 Abbreviation**

MOC: Material of Construction

SS: Stainless Steel

RPM: Revolution per minute

AC: Alternative current

MS: Mild steel

cGMP: Current good manufacturing practice

PO: Purchase order



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**5.12 LIST OF ANNEXURES:**

Annexure No.	Document Title

**Remarks (if any):**  
\_\_\_\_\_  
\_\_\_\_\_

**Done By & Date:**

**Verified By & Date:**



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**5.13 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):**

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

**Description of deficiency:**

**Corrective action(s) taken:**

**Deviation accepted by  
(Sign/Date)**

**Deviation Approved by  
(Sign/Date)**



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**6.0 INSTALLATION QUALIFICATION FINAL REPORT:**

**6.1 SUMMARY:**

**6.2 CONCLUSION:**

**Prepared By  
Sign/ Date**

**Checked By  
Sign/ Date**



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**6.3 FINAL REPORT APPROVAL:**

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol. If applicable signature in the block below indicates that all items in this qualification report of Bin blender have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>REVIEWED BY</b>			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
<b>APPROVED BY</b>			HEAD OPERATION		
			QUALITY ASSURANCE		